

- Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, June 24, 2016.\*
6. FDA Memorandum from D. Folmer, CFSAN Chemistry Review Group, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, June 20, 2018.\*
  7. Food and Agriculture Organization of the United Nations and the World Health Organization. Principles and Methods for the Risk Assessment of Chemicals in Food. 2009. Available at [http://www.inchem.org/documents/ehc/ehc/ehc240\\_index.htm](http://www.inchem.org/documents/ehc/ehc/ehc240_index.htm). (Last accessed September 12, 2017.)
  8. Flavor and Extract Manufacturers Association Letter to Judith Kidwell (FDA, CFSAN), April 11, 2016.\*
  9. FDA Memorandum from S. Thurmond, CFSAN Toxicology Team, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, June 21, 2018.\*
  10. Boobis, A.R. et al. (2006). "IPCS Framework for Analyzing the Relevance of a Cancer Mode of Action for Humans." *Critical Reviews in Toxicology*, 36:10, 781–792.
  11. FDA Memorandum from S. Thurmond, CFSAN Toxicology Team, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, June 21, 2018.\*
  12. National Toxicology Program. Report on Carcinogens Background Document for Ethyl Acrylate. December 2–3, 1998.
  13. FDA Memorandum from J. Zang, CFSAN Toxicology Team, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, June 21, 2018.\*
  14. FDA Memorandum from A. Khan, CFSAN Toxicology Team, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, June 21, 2018.\*
  15. FDA Memorandum from N. Anyangwe, CFSAN Toxicology Team, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, June 21, 2018.\*
  16. Da Rocha, M.S., Dodmane, P.R., Arnold, L.L., et al. (2012). "Mode of Action of Pulegone on the Urinary Bladder of F344 Rats." *Toxicological Sciences*, kfs035.
  17. FDA Memorandum from T. Tyler, CFSAN Toxicology Team, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, June 27, 2018.\*

#### List of Subjects

##### 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

##### 21 CFR Part 177

Food additives, Food packaging. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 172 and 177 are amended as follows:

#### PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for part 172 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 348, 371, 379e.

##### § 172.515 [Amended]

■ 2. Amend § 172.515(b) by removing the entries for "benzophenone; diphenylketone," "ethyl acrylate," "eugenyl methyl ether; 4-allylveratrole; methyl eugenol," "myrcene; 7-methyl-3-methylene-1,6-octadiene," "pulegone; *p*-menth-4(8)-en-3-one," and "pyridine."

#### PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

■ 3. The authority citation for part 177 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348, 379e.

##### § 177.2600 [Amended]

■ 4. In § 177.2600(c)(4)(iv), remove the entry for "diphenyl ketone."

Dated: October 2, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–21807 Filed 10–5–18; 8:45 am]

**BILLING CODE 4164–01–P**

#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

##### 33 CFR Part 165

[Docket Number USCG–2018–0682]

RIN 1625–AA00

#### Safety Zone; North Hero-Grand Isle Bridge, Lake Champlain, VT

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary interim rule and request for comments.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for the navigable waters within a 50 yard radius from the center of the North Hero-Grand Isle Bridge, on Lake Champlain, VT. The safety zone is necessary to protect personnel, vessels, and marine environment from potential hazards created by the demolition, subsequent removal, and replacement of the North Hero-Grand Isle Bridge. When enforced, this regulation prohibits entry of vessels or persons into the safety zone unless authorized by the Captain of the

Port Northern New England or a designated representative.

**DATES:** This rule is effective without actual notice from October 9, 2018 through September 1, 2022. For purposes of enforcement, actual notice will be used from October 1, 2018 through October 9, 2018.

Comments and related material must be received by the Coast Guard on or before January 7, 2019.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2018–0682 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule. You may submit comments identified by docket number USCG–2018–0575 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the "Public Participation and Request for Comments" portion for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email LT Matthew Odom, Waterways Management Division, U.S. Coast Guard Sector Northern New England, telephone 207–347–5015, email [Matthew.T.Odom@uscg.mil](mailto:Matthew.T.Odom@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR	Code of Federal Regulations
COTP	Captain of the Port
DHS	Department of Homeland Security
FR	Federal Register
TIR	Temporary Interim Rule
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

##### II. Background Information and Regulatory History

On July 5, 2018, Sector Northern New England was made aware by Cianbro Corporation through email, of the North Hero-Grand Isle Bridge replacement project, which will be replacing Bridge 8 on US 2 over Lake Champlain which connects the towns of North Hero Island and Grand Isle in Vermont. The COTP Northern New England has determined that the potential hazards associated with the bridge replacement project will be a safety concern for anyone within the work area.

The Coast Guard is publishing this rule to be effective, and enforceable, through September 1, 2022, in case the project is delayed due to unforeseen circumstances. During this project, removal and replacement of the bridge will take place. No vessel or person will be permitted to enter the safety zone without obtaining permission from the

COTP or a designated representative. The safety zone will be enforced during different periods during bridge deconstruction, temporary bridge installation, and construction of the permanent structure. Unless there is an emergency, the Coast Guard will issue a Broadcast Notice to Mariners via marine channel 16 (VHF-FM) 24 hours in advance of any period of enforcement. If the project is completed prior to September 1, 2022, enforcement of the safety zone will be suspended and notice given via Broadcast Notice to Mariners, Local Notice to Mariners, or both.

The Coast Guard is issuing this temporary interim rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM with respect to this rule because doing so would be impracticable and contrary to the public interest. The late finalization of project details did not give the Coast Guard enough time to publish an NPRM, take public comments, and issue a final rule before the construction work is set to begin. It would be impracticable and contrary to the public interest to delay promulgating this rule as it is necessary to establish this safety zone on October 1, 2018 to protect the safety of the waterway users, construction crew, and other personnel associated with the replacement project. A delay of the replacement project to accommodate a full notice and comment period would delay necessary operations, result in increased costs, and delay the date when the replacement project is expected to be completed and reopen the bridge for normal operations.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. For reasons stated in the preceding paragraph, delaying the effective date of this rule would be impracticable and contrary to the public interest because timely action is needed to respond to the potential safety hazards associated with the construction project.

### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The

COTP Northern New England has determined that potential hazards associated with the bridge replacement project scheduled from October 1, 2018 through September 1, 2022 will be a safety concern for anyone within the work zone. This rule is needed to protect personnel, vessels, and the marine environment on the navigable waters of Lake Champlain while the bridge replacement project is completed.

### IV. Discussion of Comments, Changes, and the Rule

This rule establishes a safety zone from October 1, 2018 through September 1, 2022. The safety zone will cover all navigable waters from surface to bottom within a 50 yard radius from the center of the Route 2 North Hero-Grand Isle Bridge. When enforced, no vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

The Coast Guard will notify the public and local mariners of this safety zone through appropriate means, which may include, but are not limited to, publication in the **Federal Register**, the Local Notice to Mariners, and Broadcast Notice to Mariners via marine Channel 16 (VHF-FM) in advance of any enforcement.

### V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

#### A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive order 13771.

The Coast Guard has determined that this rulemaking is not a significant regulatory action for the following reasons: (1) The safety zone only impacts a small designated area of Lake Champlain, (2) the safety zone will only

be enforced when work equipment is present in the navigable channel as a result of bridge removal and replacement operations or if there is an emergency, (3) persons or vessels desiring to enter the safety zone may do so with permission from the COTP Northern New England or a designated representative. The Coast Guard will notify the public of the enforcement of this rule via appropriate means, such as via Local Notice to Mariners and Broadcast Notice to Mariners via marine channel 16 (VHF-FM).

#### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A., this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

### C. Collection of Information

This temporary interim rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

### E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone that will prohibit entry within a 50 yard radius from the

center of the North Hero-Grand Isle Bridge during its removal and replacement. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01.

A preliminary Record of Environmental Consideration for Categorically Excluded Actions is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this temporary interim rule.

### G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

### VI. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <http://www.regulations.gov/privacyNotice>.

Documents mentioned in this TIR as being available in the docket, and all public comments, will be in our online docket at <http://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–0682 to read as follows:

#### § 165.T01–0682 Safety Zone—North Hero-Grand Isle Bridge, Lake Champlain, VT.

(a) *Location.* The following area is a safety zone: All navigable waters on Lake Champlain, within a 50-yard radius of the center of the North Hero-Grand Isle Bridge that spans Lake Champlain between North Hero Island and Grand Isle in position 44°45'57" N, 073°17'20" W (NAD 83).

(b) *Definitions.* As used in this section:

(1) *Designated representative* means any Coast Guard commissioned, warrant, petty officer, or any federal, state, or local law enforcement officer who has been designated by the Captain of the Port (COTP) Northern New England, to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) *Official patrol vessels* means any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP Northern New England to enforce this section.

(c) *Effective and enforcement period.* This section is enforceable 24 hours a day from October 1, 2018, through September 1, 2022. When enforced as deemed necessary by the Captain of the Port (COTP) Northern New England, vessels and persons will be prohibited from entering this safety zone unless granted permission from the COTP Northern New England or the COTP's designated representative.

(d) *Regulations.* When this safety zone is enforced, the following regulations, along with those contained in § 165.23 apply:

(1) No person or vessel may enter or remain in this safety zone without the permission of the Captain of the Port (COTP) Northern New England or the COTP's designated representative. However, any vessel that is granted permission to enter or remain in this zone by the COTP or the COTP's designated representative must proceed through the zone with caution and operate at a speed no faster than that speed necessary to maintain a safe course, unless otherwise required by the Navigation Rules.

(2) Any person or vessel permitted to enter the safety zone shall comply with the directions and orders of the COTP or the COTP's designated representative. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing lights, or other means, the operator of a vessel within the zone shall proceed as directed. Any person or vessel within the safety zone shall exit the zone when directed by the COTP or the COTP's designated representative.

(3) To obtain permission required by this regulation, individuals may reach the COTP or the COTP's designated representative via Channel 16 (VHF-FM) or (207)741-5465 (Sector Northern New England Command Center).

(e) *Penalties.* Those who violate this section are subject to the penalties set forth in 33 U.S.C. 1232.

(f) *Notification.* Coast Guard Sector Northern New England will give notice through the Local Notice to Mariners and Broadcast Notice to Mariners for the purpose of enforcement of temporary safety zone.

Dated: September 17, 2018.

**B.G. LeFebvre,**

*Captain, U.S. Coast Guard, Captain of the Port, Sector Northern New England.*

[FR Doc. 2018-21867 Filed 10-5-18; 8:45 am]

**BILLING CODE 9110-04-P**

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## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 36

RIN 2900-AO65

#### Loan Guaranty: Ability-to-Repay Standards and Qualified Mortgage Definition Under the Truth-in-Lending Act

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Agency determination; status of interim final rule.

**SUMMARY:** The Department of Veterans Affairs (VA) published an interim final rule on May 9, 2014, implementing provisions of the Dodd-Frank Wall

Street Reform and Consumer Protection Act (the Dodd-Frank Act). This document informs the public that VA will not be publishing a final rule to adopt the provisions in the interim final rule that published on May 9, 2014. However, VA will be publishing a separate regulation in the near future that will supersede the provisions in the interim final rule that published on May 9, 2014.

**DATES:** This document is effective October 9, 2018.

**FOR FURTHER INFORMATION CONTACT:** Greg Nelms, Assistant Director (26), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 632-8795. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** On May 9, 2014, VA published in the **Federal Register** (79 FR 26620) its interim final rule (IFR) pursuant to the Dodd-Frank Act, Public Law 111-203, 124 Stat. 1376 (2010). Among other things, the Dodd-Frank Act established many reforms to Federal oversight of residential mortgage lending, including a requirement that lenders be able to demonstrate that, at the time a mortgage loan is made to a borrower, the borrower is reasonably able to repay the mortgage loan. Public Law 111-203, sec. 1411 (codified at 15 U.S.C. 1639c). Such mortgage loans are referred to generally as qualified mortgages (QMs).

VA specified in the IFR that almost all VA loans meeting VA's underwriting standards would be considered safe harbor QMs. 79 FR 26622-26623. The loans that would not be considered safe harbor QMs would be certain Interest Rate Reduction Refinance Loans (IRRRLs), specifically those meeting the requirements for guaranty but failing to meet IRRRL-specific seasoning and recoupment requirements for safe harbor protections. While these types of IRRRLs could still be deemed QMs, they would receive the designation of rebuttable presumption QM rather than safe harbor QM. 79 FR 26624. VA also specified income verification requirements for IRRRLs. Id.

VA received a total of 22 comments on the IFR. Most of the commenters were industry participants in the VA Home Loan program or representatives of the lending community. A few individuals also commented. No comments were received from veterans' service organizations or veterans expressing concerns about the use of their VA home loan benefit. Most commenters sought clarification of the IFR. Several commenters were fully supportive of the rule. VA appreciates the comments received on the IFR.

On May 24, 2018, section 309 of Economic Growth, Regulatory Relief, and Consumer Protection Act (Pub. L. 115-174) superseded certain elements of the IFR. The law's seasoning and recoupment requirements for IRRRLs effectively eliminated the category of rebuttable presumption QM. Section 309 also imposed other requirements that, while not in conflict with the IFR, were not contemplated at the time of the IFR's publication. Consequently, rather than finalizing the IFR, VA will need to revise its qualified mortgage criteria in a future rulemaking. VA will in its future rulemaking take into account the spirit of the comments submitted in response to the IFR. Until such future rulemaking is final, the IFR remains in effect. To the extent any provision of the IFR conflicts with or is superseded by Public Law 115-174, Public Law 115-174 controls.

On May 25, 2018, VA released a policy guidance update in Circular 26-18-13 to inform program participants about the impact of Public Law 115-174 on VA home loan financing. Loan applications taken on or after May 25, 2018 must meet the requirements of the new law to be eligible for guaranty by the VA.

#### Signing Authority

The Secretary of Veterans Affairs approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on September 26, 2018, for publication.

Dated: September 26, 2018.

**Jeffrey M. Martin,**

*Impact Analyst, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.*

[FR Doc. 2018-21370 Filed 10-4-18; 4:15 pm]

**BILLING CODE 8320-01-P**

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R02-OAR-2018-0549, FRL-9984-58-Region 2]

#### Approval and Promulgation of Implementation Plans; New Jersey; Elements for the 2008 8-Hour Ozone National Ambient Air Quality Standards

**AGENCY:** Environmental Protection Agency (EPA).